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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/728,090 | 12/05/2003 | Giuseppe C. Viscomi | 2965-186 | 7305 |

6449 7590 09/19/2005

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EXAMINER

KIFLE, BRUCK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1624

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/728,090

Applicant(s)

VISCOMI ET AL.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 06/08/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

The disclosure is objected to because of the following informalities: A brief description of the drawings is not present.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 6-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) The process claim 6 is drawn to making all three polymorphic forms. It is unclear how a single process can result in a multitude of products. A clarification is requested.
- i) In claims 21-25, the “predetermined amount” is unknown. Such language is manifestly indefinite. Furthermore, claims 21, 23 and 25 are independent claim. It is unclear whether the rifaximins therein are the same as claimed in claims 1-5 or not. A clarification is requested. ii) In claims 29-31, it appears that Applicants intention is a pharmaceutical composition. Insertion of the term “pharmaceutical” is suggested to distinctly claim what is intended.
- iii) Claim 32 is unclear as to the scope. This claim has only rifaximin α in it. Therefore, the claim is a duplicate of claim 1.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Cannata et al. (US 4,557,866). The claims read on the compounds of Example 1, 4, 6-14 of the reference.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Marchi et al. (US 4,341,785). The claims read on the compounds of Example 6 of the reference.

Applicants are advised that In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) states: "Where, as here, the claimed and prior art product is identical or substantially identical, or is produced by an identical or substantially identical process, the PTO can require an applicant to prove that the prior art product does not necessarily or inherently possess the characteristics of his claimed product.... Whether the rejection is based on 'inherency' under 35 USC 102, on 'prima facie obviousness' under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted]."

Note, also, "products which are merely different forms of known compounds, notwithstanding that some desirable results are obtained therefrom, are unpatentable where products have same utility as the art compounds;" invention can be present if prior art product cannot be used for purpose asserted for pure or new form of product; merely changing form, purity, color, or other characteristic of old product without a new use as a result thereof does not render product patentable where utility remains the same; stability of product does not confer patentability thereon even though a new result is asserted; moreover, advantages in use of product cannot be considered of patentable significance. Ex parte HARTOP (139 USPQ 525).


Applicants must prove that the prior art process does not produce their compounds.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
September 16, 2005